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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,091	10/16/2003	Robin Douglas Clark	R0133B-REG	9099

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ROCHE PALO ALTO LLC
PATENT LAW DEPT. M/S A2-250
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EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,091

Applicant(s)

CLARK ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 30-35 is/are rejected.
- 7) ☒ Claim(s) 7-29 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/16/03&3/15/04&9</u> . | 6) <input type="checkbox"/> Other: ____. |

Claims 1-6, 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Structural makeup of "acyl" for R1-R4 variables is completely unknown. Acyl is a general term pertaining to carbonyl-derived moieties as well as other types such as sulfonyl, arsenoyl, phosphonyl, etc. Specification provides no guidance as to what might be intended much less how such divalent moieties are further substituted or how they are attached to the indole nucleus.

Claims 31-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating schizophrenia, depression and enhancing cognitive memory, does not reasonably provide enablement for remaining uses covered by these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The notion that simply having the ability to antagonize at 5HT6 receptor sites will enable the treatment of all CNS disorders, neurological disorders such as Alzheimer's or Huntington's Disease or gastrointestinal disorders or obesity has not been substantiated by the current state of the art. While treating depression and

schizophrenia has been reasonably linked to 5HT6 receptor binding since drugs that treat these uses have an affinity for this receptor, there is no basis in the pharmaceutical art for asserting all the uses being claimed. See Robichaud, provided by the examiner or Bromidge (ref.C3), provided by applicants, as examples of the current state of the serotonin receptor art. The scope of memory disorders includes more than what is asserted by applicants in the specification notably on p.1 which is limited to enhancing cognitive memory which is consistent with the teaching of Bromidge as well as Rogers. There is no teaching in these references that amnestic disorders can be treated with 5-HT6 antagonists. Nor is there any teaching that treating Alzheimer's per se can be effected by such a class of antagonists. Note Rogers discusses the possibility of enhancing cognitive processes which in turn would provide **symptomatic** treatment for dementia. See p.114, right column. In searching Medline for gastrointestinal disorders or obesity and 5-HT6, no hits were found indicating evidence of one or more 5-HT6 antagonists undergoing clinical trials for these disorders. Thus the uses being urged are not all in currently available form based on the activity relied on and the specification provides only a starting point for further research. Note Genentech vs. Novo Nordisk 42 USPQ 2d 1001 especially left column at p.1005.

Note the criteria for enablement as set out in *In re Wands* cited in MPEP 2164.01(a), August 2000 edition. Thus given the level of skill in this art which is low (for the treatment of all class of disorders being claimed) and the lack of direction (i.e. art-recognized tests) provided as to what might be treatable and in what dosage compounds are to be administered, this rejection is being applied.

Claims 7-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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EB Bernhardt

Emily Bernhardt
Primary Examiner
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